PTO-1390 (Rev. 02-2005)

Approved for use through 03/31/2007. OMB 0651-0021 U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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## TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER

H0666.70007US00

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL FILING DATE PRIORITY DATE

INTERNATIONAL APPLICATION NO. PCT/JP2003/003804 27 March 2003 (27.03.2003) TITLE OF INVENTION MEDICINAL ORAL PREPARATIONS FOR COLON DELIVERY, MEDICINAL ORAL PREPARATIONS FOR TREATING COLON CANCER AND MEDICINAL ORAL PREPARATIONS FOR TREATING APPLICANT(S) FOR SATO, Shuji; GOTO, Takeshi; TANIDA, Norifumi; MENO, Tatsuya; YOSHINAGA, Takaaki DO/EO/US and YONEMURA, Keishi Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: X This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below. X The US has been elected (Article 31). Х A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) 5. is attached hereto (required only if not communicated by the International Bureau). a has been communicated by the International Bureau. b. Х is not required, as the application was filed in the United States Receiving Office (RO/US). 6. X An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)). is attached hereto. a. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) 7. X a. are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. h have not been made; however, the time limit for making such amendments has NOT expired. C. X have not been made and will not be made. d. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 9. X An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). Items 11 to 20 below concern document(s) or information included: 11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. X An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13 Х A preliminary amendment. 14. Х An Application Data Sheet under 37 CFR 1.76. 15. A substitute specification. 16. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). Other items or information: PCT Published Application, ISR (English translation), PCT/IB/301;304;308;332 forms; 20 IPER (w/English translation) Express Mail No:EV717508065US

page 1 of 2

DATE OF MAILING: 22 SEPTEMBER 2005

## JC14 Rec'd PCT/PTO 22 SEP 2005

PTO-1390 (Rev. 02-2005) Approved for use through 03/31/2007. OMB 0651-0021

U.S. APPLICATION NO (1 170 M) (1863) ER (18) 5 8 6 INTERNATIONAL APPLICATION NO. PCT/JP2003/003804							ATTORNEY'S DOCKET NUMBER: H0666.70007US00		
The following fees have been submitted							CALCULATIONS	PTO USE ONLY	
21. X Basic national fee (37 CFR 1.492(a))\$300						\$	300.00		
22. X Examination fee (37 CFR 1.492(c))									
If the written opinion prepared by the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$ 0 All other situations \$200						\$	200.00		
23. X Search fee (37 CFR 1.492(b))									
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)						\$	400.00		
TOTAL OF 21, 22 and 23 =							900.00		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.									
Total Sheets				of each additional 50 or fraction f (round up to a whole number RATE					
47 - 100 =	/50 =				x \$250.00		0.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).									
CLAIMS	NUMBER FI	ILED -	NUMBER EXTRA	R	ATE	<u> </u>			
Total claims	36 - 2		16	×	50.00	\$	800.00		
Independent claims 3 - 3 = 0 x					0.00	\$	0.00		
MULTIPLE DEPENDENT CLAIM(s) (if applicable) +						\$			
TOTAL OF ABOVE CALCULATIONS =						\$	1700.00		
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.						\$			
SUBTOTAL =						\$			
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).						\$			
TOTAL NATIONAL FEE =						\$ 1700.00			
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property						\$ 40.00			
TOTAL FEES ENCLOSED =							\$ 1740.00		
							ount to be nded:	\$	
							ount to be rged:	\$	
a. X A check in the amount of \$ 1740.00 to cover the above fees is enclosed.									
b. Please charge my Deposit Account No. 23/2825 in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.									
c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any									
overpayment to Deposit Account No23/2825 A duplicate copy of this sheet is enclosed.									
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.									
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to review (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.  SEND ALL CORRESPONDENCE TO:									
Wolf, Greenfield & Sacks, P.C. SIGNATURE:							V C C	nam	
600 Atlantic Avenue Boston, Massachusetts 02210-2206 Tel. (617) 646-8000  John R. Van Ams						terda	ım		
CUSTOMER NU	MBER:	236	28	NAME					
				40,21 REGIS	12 STRATION N	UMBI	ER		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re International Application of SATO, Shuji et al

International Serial No.: PCT/JP2003/003804

International Filing date: March 27, 2003

For: MEDICINAL ORAL PREPARATIONS FOR COLON DELIVERY, MEDICINAL ORAL PREPARATIONS FOR TREATING COLON CANCER AND MEDICINAL ORAL PREPARATIONS FOR TREATING COLITIS

## VERIFICATION OF TRANSLATION

Honorable Commissioner of Patents and Trademarks Washington D.C. 20231

## Sirs:

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KUZUWA, Kiyoshi residing at T & T Bldg., 8-21, Tomihisacho, Shinjuku-ku, Tokyo, Japan, declares:

- (1) that he knows well both Japanese and English languages;
- he translated the above-identified (2) that International Application from Japanese to English;
- that the attached English translation is a true of the above-identified and correct translation International Application to the best of his knowledge and belief; and
- (4) that all statements made of his own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 USC 1001, and that such false statements may jeopardize the validity of the application or any patent issuing thereon.

Angust 24, 2005

| C. | C. |
| KUZUWA, Kiyoshi